

KO31003

510(k) Summary

1.0 Date Prepared

APR 11 2003

March 28, 2003

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name: Stimulation / Dissection Instruments (Tradenames have not been finalized at this time)
Common Name(s): Nerve Stimulator / Locator
Classification Name(s): Surgical Nerve Stimulator / Locator

4.0 Device Classification

Classification Name: Surgical Nerve Stimulator / Locator and accessories		
Procode 77ETN	Class II	21 CFR § 874.1820
Procode Various	Class I	21 CFR § 874.4420
Procode Various	Class I	21 CFR § 878.4800

5.0 Device Description

The designs of the Stimulus - Dissection Instruments are similar to existing stainless steel manual surgical instruments. The instruments consist of scissors, forceps, retractors, awls, taps, needles, probes, and hooks with biocompatible electrical insulation applied to selected portions, and proximal connectors provided to attach the instruments to a monopolar stimulator. The distal surfaces of the instruments are non-insulated stainless steel to provide for mechanical, manual dissection / resection, and tissue stimulation. The Stimulus - Dissection Instruments are a protected pin design and meet the requirements of IEC 60601-1:1988 /A1:1991 /A2:1995 Clause 56.3(c) per 21 CFR 898.12. Accessories include monopolar cables available in lengths up to 3 M.

6.0 Indications for Use

The Stimulus-Dissection Instruments are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

510(k) Summary (*continued*)

7.0 Substantial Equivalence

The design, technology, features, function, and intended use of the Stimulus-Dissection Instrument is substantially equivalent to Medtronic Xomed Stimulus Dissection Instruments cleared via K014165 and Medtronic Xomed Monopolar Stimulator Probes originally described in K992869.

Characteristic	Stimulus - Dissection Instruments [Proposed Device]	Stimulus / Dissection Instruments [K014165]
Indications For Use	Tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	Tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.
Stainless steel construction	Yes	Yes
Electrical insulation	Electrical insulation on all surfaces not intended to provide electrical contact with the patient	Electrical insulation on all surfaces not intended to provide electrical contact with the patient
Distal stainless steel patient contact surface	Yes	Yes
Proximal stimulator connector	Yes	Yes
IEC 60601-1 Protected Pin design	Yes	Yes
Biocompatible	Yes	Yes
Single Use, Sterile	Yes	Yes [K992869]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2003

Medtronic Xomed, Inc.
c/o Mr. Martin D. Sargent
Regulatory Affairs Manager
6743 Southpoint Drive North
Jacksonville, FL 32216

Re: K031003

Trade/Device Name: Stimulus/Dissection Instruments, Ball-Tip Probes
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: March 28, 2003
Received: March 31, 2003

Dear Mr. Sargent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Martin D. Sargent

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031003

Device Name: Stimulus - Dissection Instruments

Indications for Use:

The Stimulus - Dissection Instruments are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Or

Over-the-Counter Use _____

(Optional Format 1-2-96)

Karen H. Baker
(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K031003